

**REMARKS**

**I. Status of the Claims**

Prior to this amendment, claims 33-60 are pending, with claims 57-60 being withdrawn from consideration by the Examiner as directed to non-elected subject matter. Applicants acknowledge, with appreciation, the indication of allowability of claims 37-41.

In this amendment, claims 34 and 49 have been cancelled without prejudice or disclaimer. Therefore, claims 33, 35-48, and 50-56 are now pending and under consideration. In addition, claims 33, 43, and 57 have been amended to recite that the claimed NiTi alloy transforms from an austenite phase to a martensite phase upon the application of stress in an amount greater than 50ksi. Support for this amendment may be found in the as-filed specification and claims, for example, original claims 9 and 23. In addition, claim 50 has been amended so as to depend from a pending claim. Accordingly, Applicants submit that these amendments raise no issue of new matter.

**II. Disposition of Claims**

Claims 43, 45, 51, 53, and 56 stand rejected under 35 U.S.C. §102(b) as anticipated by U.S. Patent No. 4,665,906 ("Jervis").

Claims 49, 50, and 52 stand rejected under 35 U.S.C. §103(a) as unpatentable over Jervis. Claims 54 and 55 stand rejected under 35 U.S.C. §103(a) as unpatentable over Jervis in view of U.S. Patent No. 4,969,890 ("Sugita").

Claims 33-36 and 42 stand rejected under §103(a) as unpatentable over Jervis in view of U.S. Patent No. 4,310,354 ("Fountain") or U.S. Patent No. 4,631,094 ("Simpson").

Claims 43-53 and 56 stand rejected under §103(a) as unpatentable over Fountain in view of U.S. Patent No. 4,503,569 ("Dotter") or Sugita.

Claims 43-45, 48-53, and 56 stand rejected under §103(a) as unpatentable over Simpson in view of Dotter or Sugita.

Claims 54 and 55 stand rejected under §103(a) as unpatentable over either Fountain or Simpson in view of Sugita.

Finally, claims 43-56 stand rejected under the judicially created doctrine of non-statutory obviousness double patenting as unpatentable over claims 1-36 of U.S. Patent No. 5,318,527 ("Hyde").

Applicants respectfully disagree with and traverse each of these rejections for at least the reasons set forth in the following remarks.

## **II. Response to Art Rejections**

### **A. Rejection under §102(b)**

Claims 43, 45, 51, 53, and 56 stand rejected under 35 U.S.C. §102(b) as anticipated by Jervis. Office Action, page 3. According to the Examiner, Jervis discloses a Ni-Ti-V alloy that displays stress induced martensite at 35-40 degrees C and exhibits up to 5% recoverable strain. *Id.* From this, the Examiner concludes that this alloy anticipates claims 43, 45, 51, 53, and 56. Applicants respectfully disagree for at least the following reasons.

To establish a *prima facie* case of anticipation under 35 U.S.C § 102, the Examiner must demonstrate that the reference teaches each and every claim limitation. See M.P.E.P § 2141. Indeed, a claim is anticipated under § 102 only if each and every

element, as set forth in the claim, is found in a single prior art reference. M.P.E.P. § 2131. Applicants respectfully submit that the Examiner has not met this burden for at least the following reasons.

As amended above, claim 43 recites, *inter alia*, a ternary alloy that transforms from an austenite phase to a martensite phase upon the application of stress in an amount **greater than 50 ksi**. Claim 43 (emphasis added). Jervis, on the other hand, discloses an NiTi alloy that transforms from an austenite phase to a martensite phase at a stress of **50 ksi or less**. Indeed, Jervis states,

[t]he recoverable deformation associated with the formation and reversion of stress-induced martensite has been referred to as pseudoelasticity. While  $\sigma_m$  may be comparatively high, e.g. 50 ksi,  $\sigma_a$  is usually substantially lower, e.g. less than 10 ksi...

Jervis, column 3, line 67-column 4, line 9 (emphasis added).

Jervis clearly fails to teach each and every limitation of present claim 43. Accordingly, the 35 U.S.C. §102(b) rejection of claim 43 as anticipated by Jervis is improper, and should be withdrawn. Moreover, as claims 45, 51, 53, and 56 depend from claim 43, the §102(b) rejection of these claims is also improper, and should be withdrawn.

**B. Rejections under 35 U.S.C. §103(a)**

**1. Claims 49, 50, and 52**

Claims 49, 50, and 52 stand rejected under 35 U.S.C. §103(a) as unpatentable over Jarvis. Office Action, page 4. As claim 49 has been cancelled herein, this rejection is moot. However, as the limitations of previous claim 49 have been incorporated into present claim 43, insofar as the Examiner may apply similar reasoning to present claim 43, Applicants submit the following remarks.

According to the Examiner, Jarvis fails to disclose the specifically claimed transformation stress. *Id.* Despite this deficiency, the Examiner argues that the claimed invention is not patentable over Jarvis. *Id.* Specifically, the Examiner asserts that because the superelastic alloy of Jarvis “**may be the same** as used in the present invention, it is a reasonable assumption that its properties, such as transformation stress level, would likewise be the same [as that of the claimed invention.]” *Id.* (emphasis added) In other words, the Examiner asserts that the claimed transformation stress level is *inherently possessed* by the superelastic alloy disclosed by Jarvis. Applicants respectfully disagree for at least the following reasons.

First, Applicants submit that the Examiner’s argument is inconsistent with the teachings of Jarvis, as explained above, e.g., Jarvis does not teach a NiTi alloy having a transformation stress of greater than 50 ksi, as claimed. If Jarvis teaches anything relevant, it is NiTi alloys having a transformation stress of **50 ksi or less**. In other words, Jarvis teaches away from the claimed invention, which is known to be indicia of unobviousness. See, e.g., *In re Laskowski*, 10 USPQ 2d 1397 (Fed. Cir. 1989)(holding that it is improper to combine references if their combination would result in the

destruction of the intended operation or if a reference teaches away from the claimed invention).

Second, Applicants submit that the Examiner's argument is insufficient to establish a prima facie case of inherency, and therefore the burden of rebuttal has not shifted to Applicants. In support of this argument, the Examiner is respectfully directed to M.P.E.P § 2112 (IV), which states, *inter alia*:

The fact that a certain result or characteristic **may** occur or be present in the prior art is **not** sufficient to establish the inherency of that result or characteristic. *In re Rijckaert*, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993).

Further, the Examiner is respectfully directed to the title of M.P.E.P § 2112 (V), which makes abundantly clear that the burden shifts to Applicants to rebut a rejection based on inherency **only after** the Examiner has provided "a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic **necessarily** flows from the teachings of the applied prior art." *Ex parte Levy*, 17 U.S.P.Q.2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) (emphasis added). This the Examiner has not done.

The Examiner's assertion that the alloy of Jervis exhibit the claimed properties because they may be the same as the claimed alloys is legally deficient for the previously stated reasons. Moreover, Applicant's submit that the Examiner's rationale is technically deficient for the following reasons.

As disclosed in the present specification, the amount of stress necessary to transform a superelastic NiTi alloy from an austenite phase to a martensite phase is dependant on both the composition of the alloy and the manner in which the alloy is

processed. See specification, pages 18-20. First, in superelastic NiTi alloys, transformation stress may be tailored by controlling the amount of Ni in the alloy. *Id.* For example, adding Ni to the alloy in amounts above equiatomic amounts with Ti and other alloying elements increases the stress levels at which the stress-induced austenite-to-martensite transformation occurs. *Id.* Second, the austenite to martensite transformation stress exhibited by an NiTi alloy may be fixed by heat treating the alloy. *Id.*

Applicants note, however, that Jervis is silent with respect to the specific composition of the disclosed superelastic NiTi alloys, and certainly does not teach controlling the amount of Ni in the alloy so as to obtain an alloy that exhibits the claimed transformation stress. Moreover, Jervis is silent with respect to the manner in which the disclosed alloy is produced, and certainly does not teach thermo-mechanically processing a NiTi alloy so as to fix the transformation stress exhibited by the alloy within the claimed range. If anything, Jervis would lead one to a composition and process of making it that has a lower transformation stress than claimed.

The mere fact that Jervis discloses a ternary superelastic NiTi alloy that may comprise the same elements as the claimed invention is insufficient to reasonably support the conclusion that the disclosed alloy *necessarily* possesses the claimed transformation stress. Indeed, the mere fact that a certain thing **may** result from a given set of circumstances **is insufficient** to establish a prima facie case of inherency. *In re Robertson*, 169 F.3d 743, 745 (Fed. Cir. 1999) (emphasis added). Accordingly, Applicants submit that any rejection of present claims 33, 50 and 52 under 35 U.S.C. §103(a) as unpatentable over Jervis would be improper.

## **2. Claims 54 and 55**

Claims 54 and 55 stand rejected under 35 U.S.C. §103(a) as unpatentable over Jervis in view of Sugita. Office Action, page 4. The Examiner, acknowledging that Jervis does not specify a proximal portion coated with polymeric material, as claimed, relies on Sugita to cure this deficiency. *Id.* Noting that Sugita teaches coating an NiTi alloy catheter with a polymeric coating, the Examiner asserts that it would have been obvious to one of ordinary skill in the art at the time the invention was made to coat the proximal portion of the medical device of Jervis with the polymeric coating of Sugita, with a reasonable expectation of success. *Id.* at 4, 5. Applicants respectfully disagree with a traverse this rejection for at least the following reasons.

As noted above, Jervis fails to teach, either expressly or inherently, a ternary superelastic NiTi alloy that exhibits the claimed transformation stress. While Sugita may teach or suggest other elements of the claimed invention, Sugita does not teach or suggest an alloy exhibiting the claimed transformation stress. Moreover, Sugita, does not provide any teaching or suggestion that would have motivated one of ordinary skill in the art at the time the invention was made to modify the alloy disclosed by Jervis so as to exhibit the claimed transformation stress. In other words, Sugita does not cure the deficiencies of Jervis. Thus, Applicants submit that the rejection of claims 54 and 55 under 35 U.S.C. §103(a) as unpatentable over Jervis in view of Sugita is improper, and should be withdrawn.

### **3. Claim 33-36 and 42**

Claims 33-36 and 42 stand rejected under 35 U.S.C. §103(a) as unpatentable over Jarvis in view of Fountain or Simpson. Office Action, pages 5, 6. Although the Examiner acknowledges that Jarvis does not disclose the claimed processing steps and transformation stress, the Examiner asserts that: a) because the Applicants have not established that the claimed processing steps result in a materially different product from that disclosed in the prior art; and b) because the NiTiV alloy disclosed by Jarvis may be the same as the claimed alloy, it is reasonable to assume that the alloy disclosed by Jarvis will possess the claimed transformation stress. *Id.* at 5. Applicants respectfully disagree for at least the following reasons.

Neither Fountain nor Simpson cure the previously described deficiencies of Jarvis. Like Sugita, these references are silent with respect to superelastic NiTi alloys exhibiting the claimed transformation stress. Moreover, Applicants submit that there is no teaching in these references that would motivate one of ordinary skill in the art to modify the ternary NiTi alloy disclosed by Jarvis, by processing or otherwise, so as to exhibit the claimed transformation stress. Accordingly, Applicants submit that the 35 U.S.C. §103(a) rejection of claims 33-36 and 42 as unpatentable over Jarvis in view of Fountain or Simpson is improper, and should be withdrawn.



**4. Claims 43-45, 48-53, and 56**

Claims 43-53 and 56 stand rejected under 35 U.S.C. §103(a) as unpatentable over Fountain in view of Dotter or Sugita. Office Action, pages 6, 7. Further, claims 43-45, 48-53, and 56 stand rejected under 35 U.S.C. §103(a) as unpatentable over Simpson in view of Dotter or Sugita. Applicants respectfully disagree with and traverse these rejections for at least the following reasons.

In the Office Action, the Examiner expressly acknowledges that both Fountain and Simpson fail to teach an elongated tubular member comprising a ternary superelastic NiTi alloy exhibiting the claimed transformation stress. Office Action at 6. Nonetheless, the Examiner asserts that: a) in view of the similarity in composition between the claimed invention and that of Fountain and Simpson, it is reasonable to assume that the NiTi alloys disclosed by these references will exhibit the claimed properties; and b) it would have been obvious to one of ordinary skill in the art to form the ternary superelastic NiTi alloy disclosed by Fountain or Simpson into an elongated tubular member in view of the teachings of either Dotter or Sugita. *Id.* at 6, 7. Applicants respectfully disagree with and traverse these rejections for substantially the same reasons as set forth by above.

Fountain and Simpson are silent with respect to transformation stress, and certainly silent with respect to the concentration of elements in the disclosed alloy and methods of making such alloys to achieve the claimed transformation stress. Thus, there is no tenable basis for the Examiner's assertion that the alloy disclosed by Fountain is "the same" as the claimed alloy, much less that the disclosed alloy will exhibit the claimed properties. In other words, the Examiner has not provided a

sufficient basis in fact and/or technical reasoning to reasonably support the determination that the claimed transformation stress is *necessarily* possessed by the alloys disclosed by Fountain or Simpson.

Dotter and Sugita do not cure the deficiencies of Fountain or Simpson with respect to the claimed transformation stress. Indeed, Dotter and Sugita are silent with respect to superelastic NiTi alloys exhibiting the claimed transformation stress. Moreover, Applicants submit that there is no teaching in Dotter or Sugita that would have motivated one of ordinary skill in the art at the time the invention was made to modify the ternary NiTi alloys of Fountain or Simpson so as to exhibit the claimed transformation stress. Even if Dotter and Sugita were combined with Fountain or Simpson in the manner asserted by the Examiner, the resultant combination would still fail to teach or suggest all of the limitations of the present claims.

For at least the foregoing reasons, the 35 U.S.C. §103(a) rejection of claims 43-53 and 56 as unpatentable over Fountain in view of Dotter or Sugita is improper, and should be withdrawn. In addition, the rejection of claims 43-45, 48-53, and 56 as unpatentable over Simpson in view of Dotter or Sugita is also improper, and should be withdrawn.

#### **5. Claims 54 and 55**

Claims 54 and 55 stand rejected under 35 U.S.C. §103 as unpatentable over Fountain or Simpson in view of Sugita. This rejection, like the rejections discussed above, is fundamentally flawed because it is based on the Examiner's erroneous

assertion that the prior art alloys necessarily possess the claimed transformation stress in view of the superficial similarity between the alloy compositions.

Applicants once again maintain that this assertion is incorrect for the reasons set forth above, including the fact that Sugita does not cure the deficiencies of Fountain or Simpson. Indeed, Sugita is completely silent with respect to a ternary superelastic NiTi alloy that exhibits the claimed transformation stress. Sugita does not provide any teaching or suggestion that would motivate one of ordinary skill in the art to modify the alloys disclosed by Fountain or Simpson such that they exhibit the claimed transformation stress. Thus, even if, *arguendo*, the combination of Fountain or Simpson with Sugita is considered to be proper, the resultant combination still fails to teach or suggest all of the limitations of the present claims.

Accordingly, the 35 U.S.C. §103)(a) rejection of claims 54 and 55 as unpatentable over Fountain or Simpson in view of Sugita is improper, and should be withdrawn.

### **C. Obviousness-type Double Patenting Rejection**

Claims 43-56 stand rejected under the judicially created doctrine of obviousness-type double patenting as unpatentable over claims 1-36 of Hyde. Office Action at 7, 8. The Examiner's argument is predicated on the assertion that in view of the superficial compositional similarity between the alloy of the claimed invention and that of the ternary superelastic alloy claimed by Hyde, it is reasonable to assume that the alloys claimed by Hyde will exhibit the claimed transformation stress. In other words, the

Examiner asserts that the alloys recited in the claims of Hyde inherently possess the claimed transformation stress. Applicants respectfully disagree.

As stated above, the transformation stress exhibited by a ternary superelastic NiTi alloy is not dependant merely on the identity of the elements in the alloy, but also their relative concentration, and the processing conditions used to make the alloy. The mere fact that the alloys claimed by Hyde may be superficially similar in composition to the claimed invention (in that they may contain the similar elements) is not a sufficient basis in fact or technical reasoning to reasonably support a theory of inherency. Moreover, the Examiner has provided no additional evidence or arguments as to *why* one of ordinary skill in the art, looking at Hyde alone, would have been motivated to modify the alloy compositions claimed by Hyde so as to arrive at the presently claimed invention.

Thus, Applicants submit that the rejection of claims 43-56 under the judicially created doctrine of obviousness type double patenting in view of claims 1-36 of Hyde is improper, and should be withdrawn.

**III. Conclusion**

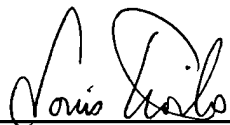
In view of the foregoing amendments and remarks, Applicant respectfully requests reconsideration and reexamination of this application and the timely allowance of the pending claims.

Please grant any extensions of time required to enter this response and charge any additional required fees to our Deposit Account no.: 06-0916.

Respectfully submitted,

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